4.0 CHEMICAL TREATMENT

4.1 GENERAL DESCRIPTION OF TECHNOLOGY

In the treatment of medical waste, antimicrobial chemicals may be used alone or in combination with encapsulating agents or mechanical destruction devices such as shredders or hammermills. The effectiveness of the treatment depends upon the characteristics of the chemical, the concentration of active ingredient, the contact time with the waste, and the characteristics of the waste being treated. Since the AOAC methods for determining the microbial efficacy of a chemical apply primarily to environmental surfaces, FIFRA registration requirements may need to be developed for evaluation of chemical agents used to treat medical waste. Classes of common antimicrobial chemicals and the advantages and disadvantages of each are found in Table 4.1.

4.1.1 Antimicrobial Chemicals

4.1.1.1 Scale of Resistance

From many years of germicide research as detailed in the published literature, a solid framework of resistance relative to the major groups of microorganisms has emerged. This general scale of resistance, from least to most resistant, is as follows: vegetative bacteria, vegetative fungi and fungal spores, viruses, mycobacteria, and bacterial spores. In regard to germicidal resistance, viruses are divided into two groups - the less resistant enveloped (lipophilic) viruses, and the more resistant nonenveloped (hydrophilic) viruses (Prince et al., 1991). The scale can be useful in the selection of germicides for specific applications. Thus, EPA registered disinfectant with a fungicidal claim also predicts effectiveness against vegetative bacteria; a tuberculocidal claim predicts effectiveness against mycobacteria, bacteria, fungi, and viruses, with the exception of bacterial spores; and a sporicidal claim predicts the inactivation of all microbial forms. Independent germicidal test research supports the concept of the resistance scale (Grabow et al., 1983; Snead et al., 1980; Liu et al., 1971; Lensing et al., 1985).

4.1.1.2 Efficacy Under FIFRA

An antimicrobial chemical can be described as an agent which destroys disease causing or other harmful microorganisms on environmental surfaces. Such chemicals are registered by the Environmental Protection Agency's Office of Prevention, Pesticides and Toxic Substances (OPPTS) according to their use against particular types of pathogens. This registration is required by the FIFRA. The EPA relies primarily on the standard methods of the AOAC and manufacturers' data for determining the efficacy of antimicrobial chemicals for killing target organisms. Several levels of antimicrobial activity are defined to indicate the types of organisms the chemical class is expected to kill. Common definitions used in selected antimicrobial efficacy claims are listed in Table 4.2.

Table 4.1 Advantages And Disadvantages Of Antimicrobial Agents

Class	Advantages	Disadvantages
Alcohols	Bactericidal Tuberculocidal Virucidal Fungicidal Non-staining Non-irritating Rapid action	Non-sporicidal Organic matter interference Incompatible with some rubber and plastics Highly flammable
Quaternary Ammonium Compounds	Bactericidal Virucidal (lipophilic) Fungicidal Pleasant odor	Non-tuberculocidal Non-sporicidal Organic matter interference Non-virucidal (hydrophilic)
Phenolic Compounds	Bactericidal Fungicidal Tuberculocidal Virucidal (lipophilic)	Questionable virucide (hydrophilic) Non-sporicidal Skin irritant Unpleasant odor Corrosiveness
Iodophor Compounds	Bactericidal Virucidal Fungicidal Detergent action Storage stability	Prolonged exposure for tuberculocidal and sporicidal activity Corrosiveness Inactivation by organic matter

Table 4.1 Advantages And Disadvantages Of Antimicrobial Agents (continued)

Class	Advantages	Disadvantages
Glutaraldehyde	Bactericidal Virucidal Fungicidal Tuberculocidal Sporicidal Lack of organic matter interference Generally non-corrosive	Irritant Limited shelf life
Hypochlorite solution (≥ 500 ppm FAC)	Bactericidal Virucidal Fungicidal Tuberculocidal	Prolonged exposure for sporicidal activity Corrosive Bleaching agent
Hydrogen peroxide	Bactericidal Virucidal Fungicidal Tuberculocidal Sporicidal	Corrosive

Source: Adapted from Cole, 1987.

Table 4.2 Selected Antimicrobial Efficacy Claims For Microbial Inactivation[1]

Specific Claim	Definition
Sporicide/Sterilant	An agent intended to inactivate all living microorganisms, especially bacterial spores.
Tuberculocide	An agent intended to inactivate mycobacteria, especially *Mycobacterium tuberculosis*. Tuberculocidal efficacy assumes inactivation of all viruses, fungi, and vegetative bacteria.
Virucide	An agent intended to destroy viruses. Virucidal efficacy may vary in regard to lipophilic and hydrophilic viruses.
Fungicide	An agent that inactivates fungi including fungal spores.
Bactericide	An agent that inactivates vegetative bacteria but not bacterial spores.
Germicide	An agent that inactivates one or more pathogenic microorganisms. (May include sporicide, tuberculocide, virucide, fungicide, or bactericide).

[1] Inactivation refers to microorganism death or injury sufficient to prevent multiplication.
Adapted from: EPA (1984)

In the United States, antimicrobial chemicals typically include products with some or all of the following claims: bactericidal, fungicidal, virucidal, tuberculocidal, and sporicidal. A tuberculocidal agent is one with demonstrated capability of killing mycobacteria or, in particular, *Mycobacterium tuberculosis*, an especially resistant organism. Some tuberculocidal agents also have the capability of inactivating bacterial spores upon prolonged exposure, and also carry a sporicidal claim.

Classes of chemicals exhibiting tuberculocidal activity include the alcohols (particularly ethyl and isopropyl aqueous solutions of 70 to 90 percent), the aldehydes (glutaraldehyde two percent, formaldehyde three to eight percent), the chlorine liberating compounds (1000 ppm or more free available chlorine [FAC]), hydrogen peroxide (six to 25 percent), iodine compounds, and some phenolics. Sporicidal activity is exhibited by the peroxides, aldehydes, and the halogens (sodium hypochlorite, chlorine dioxide, hypochlorite/alcohol mixtures, iodophors).

4.1.1.2 Application to Medical Waste Treatment

All antimicrobials used for medical waste treatment, either alone or in a mechanical/chemical treatment system, must be tested for efficacy and be currently registered under the FIFRA regulations.

4.1.2 Operational Parameters

Antimicrobial efficacy is highly dependent on the exposure time, temperature, chemical concentration, pH, degree of inactivation by interfering substances (such as hard water and organic matter), and the numbers and types of microorganisms in the challenge. Some organisms are much more innately resistant to chemical inactivation than others (e.g. *Pseudomonas aeruginosa, Mycobacterium tuberculosis*) and, in general, the greater the number of contaminating microorganisms, the longer it will take to effectively inactivate them.

4.1.2.1 Concentration/pH/Interference

Microbial inactivation by chemical agents is a function of the active ingredient concentration and pH of the prepared solution. Thus it is extremely important to assure that the chemical used will not be diluted in the treatment process beyond its intended use-dilution. Some antimicrobials (such as quaternary ammonium compounds and the halogens) may be readily inactivated when challenged by organic matter (e.g., whole blood, serum) and/or hard water (calcium and magnesium concentrations expressed as calcium carbonate). Such potential interference should be considered when selecting a formulation and its concentration for medical waste treatment.

4.1.2.2 Exposure Time/Temperature

There must be sufficient time of contact between treatment chemical and a contaminated surface in order to effectively inactivate microbial contamination. In the United States, the EPA regulates environmental antimicrobials and requires efficacy data based on standard methods that normally evaluate the ability to kill vegetative bacteria, fungi, and mycobacteria with a 10 minute exposure at 20 °C. The ability to kill bacterial spores depends on the chemical, and exposure times (normally in numbers of hours) will vary. Additionally, antimicrobial activity is potentiated by increasing temperature.

4.1.2.3 Neutralization

Of critical importance in antimicrobial studies is the use of a proper method of instantly deactivating the test chemical at the end of a specified contact time and rendering it nontoxic to exposed organisms. Care must be taken to assure that a chemical neutralizer is not of itself a toxic agent, particularly toward viable but injured organisms. For example, the toxicity to disinfectant exposed cells of many chemical neutralizers, including sodium thiosulfate, has been previously reported in the published literature (MacKinnon, 1974; Bergan and Lystad, 1972; Collins et al., 1981). For this reason, where possible, dilution in a high protein medium is preferred. ~~A list of recommended~~ neutralization techniques is shown in Table 4.3.

4.1.2.4 Waste Characteristics

Refer to Section 1.1 of this document for a general discussion on the description of medical waste and the specific classes that are suitable for each specific medical waste treatment technology.

Chemical or mechanical /chemical treatment of medical waste is suitable for most waste categories with the exception of body parts and contaminated animal carcasses that may be aesthetically unacceptable. Radioactive , hazardous , and cytotoxic waste are also excluded from treatment by chemical disinfection.

4.1.2.5 Residuals

Chemical treatment in jars does not include a destruction step in the treatment cycle, thus the solid waste remains recognizable after treatment. Mechanical/chemical systems include a waste grinding step in the procedure that appears to meet the destruction criteria of the MWTA and therefore, the solid waste debris from mechanical/chemical treatment systems are no longer recognizable. There is a liquid effluent from both chemical treatment in jars and mechanical/chemical treatment systems. The liquid effluent is frequently discharged directly to the sanitary sewer in accordance with local regulation.

Table 4.3 Selected Neutralization Techniques

Class	Agent or Process (in preferential order)
Acids/alkalies	Appropriate neutralization/dilution
Alcohols	Dilution
Chlorines	Nutrient medium Serum Sodium thiosulfate
Formaldehyde	Nutrient medium Serum Sodium bisulfite Ammonium compounds
Glutaraldehyde	Nutrient medium Glycine Sodium bisulfite
Iodophors	Polysorbate 80 Nutrient medium Sodium thiosulfate
Phenolics	Polysorbate 80 Dilution
Quaternaries	Polysorbate 80/lecithin
Hydrogen peroxide	Catalase

4.1.3 Static systems

Jars of treatment chemicals often hold less than 1 gallon of waste materials and solution. They are used in small offices and clinics (dentists, veterinarians, physicians) to treat infectious waste generated during patient visits. Solutions should be prepared to maintain the required use-dilution throughout the day. At the conclusion of the day, the solution may be decanted directly to the sanitary sewer (if permitted locally) and the solid waste material discarded with the municipal waste where permitted. Some commercially available chemical waste treatment systems may recommend an encapsulation procedure prior to disposal. Encapsulation of waste in plaster of paris, or polymer substances has not been adequately shown to be an effective method of precluding exposure during waste handling.

4.1.4 Recirculating System

4.1.4.1 Size

Recirculating mechanical/chemical treatment systems may come in a variety of sizes. Small systems (~ 3 ft x 3 ft x 4 ft) may use as little as 4 gallons of recirculating chemical. A large system may use as much as 15 gallons of recirculating chemical.

4.1.4.2 Application

Recirculating mechanical/chemical treatment systems are applicable for all sizes of medical waste generators because they come in a wide variety of sizes. They are most applicable for onsite treatment of medical waste and are seldom used as offsite commercial treatment systems.

4.1.4.3 Standard Operating Conditions

The treatment chemical is prepared according to the manufacturers' specifications and circulated through the waste each time new waste is added to the device. When new waste is added to the device it enters the grinding and shredding chamber where the treatment solution circulates through the waste. In some cases, additional chemical may be added to the solution with each waste load. At the conclusion of the grinding process the treated waste may either sit in the treatment solution for an additional period of time or the solution may be removed from the debris immediately after treatment. In either case, the treated solid debris may be discarded with the municipal waste where permitted. The liquid solution may be discharged to the sanitary sewer where permitted after a limited number of uses or in certain cases reused indefinitely with the replenishing of water and treatment chemicals with each waste load.

4.1.5 Flow-Through System

4.1.5.1 Size

Flow-through mechanical/chemical treatment systems also come in a variety of sizes. Small systems may be approximately 3 ft x 3 ft x 4 ft and the largest system occupies an entire room and has a flow rate approaching 30 gal/minute.

4.1.5.2 Application

Flow-through mechanical/chemical treatment systems are applicable for all types of medical waste generators because they come is such a wide variety of sizes. They are most applicable for onsite treatment of medical waste and are seldom used as an offsite commercial treatment systems.

4.1.5.3 Standard Operating Conditions

When waste is added to the flow-through mechanical/chemical treatment system, the treatment solution is automatically diluted to the use-concentration, added to the grinding chamber, and circulated through the waste as it is ground. At the conclusion of the grinding and treatment cycle, the solid debris are removed from the solution and after the excess solution has drained from the treated waste, the debris are discarded with the municipal waste where permitted. The liquid effluent is generated at a rate approaching 30 gal/min in the largest devices and is discharged directly to the sanitary sewer where permitted. Some locations may require a sewage discharge permit for facilities utilizing this type of treatment process.

4.2 OPERATION EVALUATION

Destructive treatment systems that grind, shred, or otherwise render the waste unrecognizable, while simultaneously treating the waste with an antimicrobial chemical, can only be evaluated for effectiveness by the demonstration of appropriate microbial kill on a per gram of waste basis. It is recommended that all chemical treatment systems demonstrate a minimum of 10^3 spore kill per gram of waste when samples are processed for recovery of test organisms.

4.2.1 Test Organism Selection

Nonpathogenic spores of *B. stearothermophilus* are recommended for use as biological indicators of chemical treatment especially if the test packs are destroyed with the waste prior to recovery. Other bacterial spores such as *B. subtilis* are commonly found in the waste stream, thus quality control procedures would require background monitoring. While a strain of *B. subtilis* spores is used in the AOAC Sporicidal Activity Test for determining sporicidal

efficacy of chemical germicides, *B. stearothermophilus* has been reported as disinfectant resistant (Sykes, 1970), is not normally found in the medical waste stream, and can be recovered easily and is more selectively isolated due to its thermophilic growth requirement. Strains of *B. stearothermophilus* and *B. subtilis* have been shown to have essentially the same inactivation profiles from exposure to chemical treatment (Cole et al., 1991).

4.2.2 Test Organism Procurement and Preparation

B. stearothermophilus ATCC 10149 and 12980 are suggested sporicidal indicators. Commercial spore suspensions at concentrations of up to 10^8 spores/mL are available.

4.2.3 Test Organism Quality Control

Commercially prepared test organisms should be stored according to manufacturers' directions and used before the indicated expiration dates.

4.2.4 Test Organism Preparation and Exposure

The test procedure involves placing a high level spore suspension in the chemical or mechanical/chemical treatment system under normal operating conditions with surrogate medical waste, and conducting the recovery of surviving spores from the treated waste solids. The test challenge should include representative organic matter (e.g., agar plates, whole blood, serum, plasma, etc.) that comprises at least 5 percent by weight of the total waste challenge.

4.2.4.1 Static Chemical Treatment

The addition of the suspended organism challenge to the antimicrobial solution should not dilute the chemical beyond its desired use-dilution. Replicate samples should be obtained for recovery at various contact times up to, at, and beyond the recommended contact time to generate a kill curve and demonstrate progressive spore kill over time. A treatment control containing sterile phosphate buffer in place of the treatment chemical should also be run with the test system as a check on spore quantitation, sampling, and recovery media and conditions.

4.2.4.2 Recirculating Systems

The total volume of liquid antimicrobial chemical used during waste processing must be considered when determining numbers of test spores needed to show there has been adequate kill of the indicator organism. Dilution of the indicator organism does not constitute treatment. Therefore, a comparative tap water control cycle with no chemical agent should be run using the indicator organism to check on spore distribution and quantitation throughout the system, as well as a check on sampling and recovery techniques.

In preparing the test load, spore suspensions should be placed within sterile containers

(e.g., polypropylene screwcapped tubes). If glass vials of spore suspensions are used, they should likewise be placed in polypropylene tubes or other similar containers to simulate microorganisms in typical waste containers.

Prior to testing with the treatment chemical, the unit should be run with tap water. When testing with water or the treatment chemical the test challenge should be placed in the device with the waste and the system started and allowed to operate automatically for one cycle. As the waste and test organisms are being processed, samples of the recirculating chemical and samples of the treated solid material should be collected in clean, sterile containers and processed for surviving organisms.

4.2.4.3 Flow-Through Systems

The initial step in the test method for flow-through mechanical/chemical treatment systems is to identify the passage of liquid effluent through the system. Food dye may be used to help identify the passage of the test organisms through the system and identify sampling times for each sampling site. The first step in the method is the identification of sampling sites.

A bottle of food dye may be added to the device and processed with tap water only flowing through the system (no disinfectant solution; no waste) to identify the sampling window. The sampling window for the test procedure includes the time the dye first appears at the sampling site to the time the dye disappears at that site.

After the sampling window has been identified, a challenge of test organisms should be added to the device and the device should be operated again with tap water and surrogate waste. Liquid effluent samples should be taken during the time period identified as the sampling window along with the solid waste samples. The results are used as a control against which microbial kill from treatment chemical exposure should be measured.

4.2.5 Organism Recovery

The samples collected in the evaluation of chemical or mechanical/chemical treatment systems should be promptly neutralized after collection. An appropriate neutralizing solution should be selected for the specific disinfectant solution. A list of appropriate neutralizing techniques is presented in Table 4.3. It is prudent to consider using two or more means of neutralization. For example, in neutralizing high concentrations of sodium hypochlorite, one may employ dilution (1:10 or greater) in a high protein broth medium that also contains 0.1 percent sodium thiosulfate.

Effective neutralization must be demonstrated before any efficacy testing is undertaken. Neutralization can be evaluated by the addition of increasing amounts of treatment chemical to replicate tubes of the neutralizer broth and then inoculating all samples

with low numbers of a sensitive vegetative organism. As an example, amounts of 0.05, 0.1, 0.3, 0.5, and 1.0 mL of the treatment chemical are added to each of the five tubes containing 10 mL of neutralizer broth. To each tube, including control tubes without treatment chemical, is added a dilution of test cells (e.g., *Staphylococcus* which is sensitive to sodium thiosulfate) that yields between 10 and 40 cells. Appropriate replicate agar plates are also inoculated before and after each tube inoculation to quantify the inoculum. All tubes and plates are then incubated at the appropriate temperature and examined for growth each day for 7 days. Growth in tubes indicates appropriate neutralization at the indicated concentration, while an absence of growth indicates residual chemical exerting a bacteriocidal or bacteriostatic effect, or toxicity of the chemical neutralizer (e.g. sodium thiosulfate).

When testing the actual treatment process, neutralized samples can be mixed and vacuum filtered through a 0.45 µm membrane. The membrane can then be washed in a phosphate buffer to remove the organisms. The resultant organism/buffer solution can be inoculated in duplicate onto an appropriate medium (such as soybean-casein digest agar), streaked for quantitation, sealed in plastic bags, and incubated at 55 °C for at least 48 hours. Alternatively, the membrane may be placed directly onto an appropriate sterile agar surface, inverted, and incubated as described.

4.2.6 Treatment Validation and Routine Testing Frequency

Antimicrobial efficacy of chemical and mechanical/chemical treatment is measured by the calculation of microbial kill per gram of treated waste. The number of organisms determined in the control (tap water) samples is compared with the mean number of organisms recovered from the test samples. The difference between them represents the number of test organisms killed per gram of treated waste solids. This can be represented as follows:

$$K = N_0 - N_2$$

Where:
- K = Mean number of test organisms killed per gram of treated waste
- N_0 = Mean number of test organisms per gram of waste recovered from the control (tap water) samples.
- N_2 = Mean number of test organisms per gram of waste recovered from the chemical treatment samples.

To validate the treatment process, multiple cycles should be tested along with appropriate control cycles. If results show less than the desired kill in the specified treatment time, then process factors (time, concentration, pH) should be checked and/or modified and the validation testing repeated until results are satisfactory. Once the appropriate operating parameters are established which ensure adequate waste treatment, at least one cycle of the process should be monitored routinely on a bi-weekly basis unless operating parameters change or major repairs are made. Operating parameters (i.e., pH, chemical concentration,

temperature) may be used to monitor daily waste processing for indications of upset conditions. Upset conditions should be recorded and maintenance performed. Testing should then be repeated.

4.2.7 Quality Control Procedures

Quality control procedures presented in Section 1.3.7 should be followed.